ISIS-3561

PATENT

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M.G.J
3/30/00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Bennett *et al.*

Serial No.: 09/315,292 **Group Art Unit: 1635**

Filed: May 20, 1999 **Examiner: M. Shibuya**

For: Compositions and Methods for the Pulmonary Delivery of Nucleic Acids

I, **Michael P. Straher**, Registration No. **38,325** certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

On March 20, 2000

Michael P. Straher, Reg. No. **38,325**

Assistant Commissioner
for Patents
Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT

This paper responds to the Office Action mailed January 18, 2000, in connection with the above-identified patent application. A request for a one month extension of time and appropriate payment is enclosed herewith.

The Office Action has required restriction among two allegedly distinct inventions:

I. Claims 1-36 and 62, pharmaceutical compositions, classifiable in class 536, subclass 24.5;

II. 37-61 and 63, drawn to methods of administration of an aerosolized nucleic acid into the lungs, and a device therefor, classifiable in class 514, subclass 44. The Office Action also requires elections among species of internucleoside linkages, genes, and antisense oligonucleotides.

As a preliminary matter, Applicants thank Examiner Shibuya for the courtesy afforded Applicants' undersigned attorney in a telephone conference on March 20, 2000, in which the current restriction requirement was discussed. In that conference, Examiner Shibuya agreed to add phosphorothioate internuceloside linkages to the list of linkages of paragraph 4 of the office action. Applicants also thank Examiner Shibuya for indicating that the three species elections levied in the Office Action are for searching purposes only.

In response to the restriction requirement, Applicants elect herein the subject matter denominated above as Group II, claims 37-61 and 63.

In response to the species elections levied to aid in searching the present invention, Applicants elect herein for claims 37-61 phosphorothioate linkages. Applicants further elect the species denoted B2 in the Office Action (gene coding for ICAM-1). For claim 63, Applicants further elect the species denoted A3 in the Office Action (ISIS-15839).

Applicants respectfully traverse the restriction requirement. The restriction requirement is improper

because the Examiner has not shown that examining all the claims would constitute a serious burden.

M.P.E.P. 803 provides:

> If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.

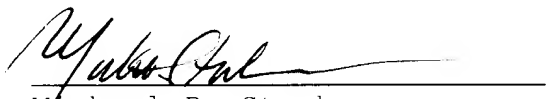
Thus, for a restriction requirement to be valid, the Examiner must establish the following two criteria: (1) the existence of independent and distinct inventions, (35 U.S.C. 121); and (2) that the search and examination of the entire application cannot be made without serious burden (M.P.E.P. 803).

The Examiner has not shown that the second requirement has been met. Specifically, examination of group I along with the elected group II would entail searching only one additional subclass in one class. Accordingly, the simultaneous search and examination of Groups I and II would pose no significant burden, and would resulting in economies to the Patent Office as well as the Applicant. Accordingly, Applicants respectfully request reconsideration of this restriction requirement.

In view of the foregoing, Applicants submit that the claims presently before the Examiner parentally define the invention over the applied art and are otherwise in condition for ready allowance. An early Office Action to

that effect is, therefore, earnestly solicited.

Respectfully submitted,



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Date: March 20, 2000

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